energy and distal end for applying that energy to the heart wall to create a channel herein, and a channel marking and drug delivery catheter subsystem connected to an imaging medium source and a source of a therapeutic or diagnostic agent and having a distal end proximate the distal end of the treatment catheter for applying both an imaging medium and the therapeutic or diagnostic agent in or proximate the channel.

Linhares is directed to a system and method of <u>marking</u> percutaneous transmyocardial revascularization channels in a human heart. Catheter 16 of *Linhares* is <u>only</u> a <u>marketing catheter</u> which is connected <u>only</u> to an <u>imaging medium source</u>. See Col. 3, line 65 – Col. 4, line 2; Col. 4, lines 21-28; and Col. 4, lines 45-47 of *Linhares*.

The Examiner states in the Office Action that "[t]he recitation that the catheter of the present invention 'is configured to decline therapeutic or diagnostic agent' is an intended use and has no structural limitation." Page 5, ¶ B of the July 29, 2003 Office Action.

However, the applicants' claim 1 includes the feature of "a channel marking and drug delivery catheter <u>subsystem connected to an imaging medium source and a source of a therapeutic or diagnostic agent</u>". Independent method claim 3 also claims introducing both an imaging medium and a therapeutic or diagnostic agent into a heart wall. This claim element is not an intended use, but a structural feature of the applicants' claimed invention. As claimed by the applicant, the channel marking and drug delivery catheter subsystem is connected to <u>both</u> an imaging medium source <u>and</u> a source of a therapeutic or diagnostic agent. *Linhares* discloses marking catheter 16 which is connected to <u>only one</u> source, the source being an <u>imaging medium source</u>. *Linhares* clearly is only connected to one source, and does not disclose, teach or suggest connecting the marking

LE-199J 2

catheter of *Linhares* to <u>two</u> sources, or that the catheter is connected to a <u>therapeutic or</u> <u>diagnostic agent</u>.

Accordingly, *Linhares* fails to disclose a channel marking and drug delivery catheter subsystem connected to an imaging medium source and a source of a therapeutic or diagnostic agent as claimed by the applicant. Therefore, the applicants submit that the Examiner's double patenting and § 102(e) rejections have been overcome.

The Examiner also rejects claims 1-3 under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,023,638 to *Swenson*.

Swenson is directed to a system and method for conducing electrophysiological testing using high-voltage energy pulses to stun tissue. Swenson discloses an instrument 312 (such as a catheter or surgical probe) having an array of electrodes 318 as well as instruments 314 and 316.

However, *Swenson* fails to disclose a channel marking and drug delivery catheter subsystem <u>having a distal end proximate the distal end of the treatment catheter</u>. As shown in Figs. 38-39 and Col. 13, lines 9-34 of *Swenson*, there is no disclosure, teaching or suggestion that instruments 314 and 316 have a distal end proximate the distal end of the treatment catheter as claimed by the applicant.

Accordingly, as *Swenson* fails to disclose all of the features of the applicants' claimed invention, *Swenson* fails to anticipate the applicants' claims.

If for any reason this Preliminary Amendment is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts, (781)890-5678.

LE-199J 3

Respectfully submitted,

Jason D. Shanske Reg. No. 43,915